

EXHIBIT G

Elaine Duncan

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. : Master File No.
PELVIC REPAIR SYSTEM : 2:12-MD-
PRODUCTS LIABILITY LITIGATION : MDL 2327
:
: JOSEPH R.
THIS DOCUMENT RELATES TO : GOODWIN
THE CASES LISTED BELOW : US DISTRICT
JUDGE

Mullins, et al. v. Ethicon, Inc.,
et al. 2:12-cv-02952
Sprout, et al. v. Ethicon, Inc.,
et al. 2:12-cv-07924
Iquinto v. Ethicon, Inc.,
et al. 2:12-cv-09765
Daniel, et al. v. Ethicon, Inc.,
et al. 2:13-cv-02565
Dillon, et al. v. Ethicon, Inc.,
et al. 2:13-cv-02919
Webb, et al. v. Ethicon, Inc.,
et al. 2:13-cv-04517
Martinez v. Ethicon, Inc.,
et al. 2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc.,
et al. 2:13-cv-07283
Oxley v. Ethicon, Inc.,
et al. 2:13-cv-10150
Atkins, et al. v. Ethicon, Inc.,
et al. 2:13-cv-11022
Garcia v. Ethicon, Inc.,
et al. 2:13-cv-14355

(Caption Continued on Next Page)

- - -

October 6, 2015
Deposition of Elaine Duncan

- - -

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1 ELAINE DUNCAN,

2 After having been first duly sworn, was called as a
3 witness and testified as follows:

4 EXAMINATION

5 BY MS. FITZPATRICK:

6 Q. Good morning, Ms. Duncan. My name is Fidelma
7 Fitzpatrick, and before we get started today, I'm going to
8 go ahead and mark some documents and give you copies so
9 you have them with you for today.

10 A. Okay.

11 , MS. FITZGERALD: So if we can mark as
12 Deposition Exhibit Number 1, it's the Notice of Deposition
13 itself.

14 (Whereupon, Exhibit 1 was marked.)

15 BY MS. FITZPATRICK:

16 Q. Let me mark this document as Exhibit 2 and ask
17 you, Ms. Duncan, if you could identify that for me?

18 (Whereupon, Exhibit 2 was marked.)

19 THE WITNESS: This is my report.

20 BY MS. FITZPATRICK:

21 Q. Okay. And so I'm correct that what I've given
22 you is a complete copy of the report that you produced in
23 this consolidated case; is that right?

24 A. Yes, ma'am, and it includes my CV.

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1 **Q.** I'm not talking -- let me just make clear.

2 I'm not talking about a single paragraph on
3 page 17. I think that I've been very explicit in what
4 I've asked you. My question concerns what you considered
5 in reaching your opinions in this case.

6 Did you consider the 510(k) application and
7 clearance process for the TVT-R device when reaching your
8 opinions in this case?

9 **A.** No, mostly because in these cases, that 510(k)
10 had already been done with the exception of blue, and of
11 course, it's a part of my job to consider whether they
12 did what their obligations were or not. I didn't look at
13 the 510(k) in order to make any determinations because
14 there's nothing in the 510(k) that would have helped me
15 with this determination.

16 **Q.** Okay. So if you turn to page 12, you cite two
17 Ethicon TVT 510(k) applications; right?

18 **A.** Let me catch up with you. Are you talking
19 about the first bullet point, for example?

20 **Q.** The first bullet point, second bullet point,
21 third bullet point, the next paragraph on page 13.

22 **A.** I was looking at the FDA's guidance documents
23 for the content of the files that I was looking at, so I
24 was trying to make sure that the due diligence -- in my

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1 due diligence review, that they had check-boxed all the
2 requirements for them. I do not mean to say that I made
3 my conclusions based on the content of the 510(k). I made
4 my conclusions that the performance testing that they did
5 to the standard, this standard that I'm citing, FDA
6 standard for surgical mesh. When I looked at the testing
7 records and the kind of information that went into that
8 submission, it was consistent with that FDA standard for
9 surgical mesh. This is how performance is judged when
10 you're looking at a standard of any type; did the data
11 conform to the standard of the realm.

12 Q. And the standard is what?

13 A. This guidance I mention here. There is no
14 international standard for surgical mesh performance other
15 than this guidance, and this guidance takes the form of a
16 standard because it sets down the requirements for
17 evaluation of the performance of any surgical mesh,
18 regardless of its application.

19 Q. Okay. So Ms. Duncan, I don't think this
20 is difficult, and I hope that I'm getting this right.

21 You looked at Ethicon's conduct here against
22 the standard, the FDA standard, which as you say is, "FDA
23 Guidance for the Preparation of a Premarket Notification
24 Application for a Surgical Mesh;" correct?

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1 510(k) requirements.

2 **A.** I'm not sure I can recall something off the
3 top of my head like that, but there are a number of
4 products that have gotten on the market through a PMA
5 supplement that has taken, certainly, less than a year,
6 and I've been personally involved in 510(k)s that take
7 longer than a year.

8 **Q.** Okay. Tell me what those are.

9 **A.** As I said, I can't recall off the top of my
10 head these PMA supplements that have been short, nor
11 can -- would I be able to refer to 510(k)s that have
12 taken longer without divulging confidential information
13 of my clients'. I'm just explaining to you, I've been
14 personally involved in 510(k)s that have taken more than
15 a year and, I think, in fact, one of them was almost two
16 years, to be clear.

17 **Q.** Okay. Now, we started this whole discussion
18 by me asking what I thought was a simple question. And
19 the simple question is, you have relied on the federal
20 regulations and the 510(k) process as part or as one of
21 the bases for your conclusion that Ethicon acted
22 appropriately in bringing the TVT to market; correct?

23 **A.** I considered it as one. I didn't rely on it.

24 **Q.** Okay. Why do you spend two pages of probably

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1 30 pages discussing the 510(k) process in detail if it's
2 not something that you relied on? Why did you choose
3 to spend this much paper doing that if it really has no
4 basis in your report?

5 Can I just scratch this whole section out?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: The question is can you
8 scratch it out?

9 BY MS. FITZPATRICK:

10 Q. Because it doesn't mean -- is it meaningless
11 in the connection with your report?

12 MR. DAVIS: Object to the form.

13 BY MS. FITZPATRICK:

14 Q. I'm trying to understand why.

15 A. It is not meaningless, but if you want to
16 scratch it out, feel free, because it would not make an
17 impact on my conclusions. If you chose to throw every
18 reference I've made to the 510(k) out of this report, my
19 conclusions would be the same.

20 Q. Okay. Well, about -- let me back up. About
21 10 minutes ago, you had a different answer, and I want to
22 make sure that I know which one is correct.

23 MR. DAVIS: Are you acknowledging that
24 you're repeating the same questions?

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1 STATE OF MINNESOTA)

2) ss

3 COUNTY OF ANOKA)

4

5 Be it known that I took the foregoing deposition
of ELAINE DUNCAN, on the 6th day of October, 2015, in
6 Minneapolis, Minnesota;

7 That I was then and there a notary public in and
for the County of Anoka, State of Minnesota, and that by
8 virtue thereof, I was duly authorized to administer an
oath;

9

10 That the witness was by me first duly sworn to
testify the whole truth and nothing but the truth relative
to said cause;

11

12 That the testimony of said witness was
recorded in Stenotype by myself and transcribed into
typewriting under my direction, and that the deposition is
13 a true record of the testimony given by the witness to the
best of my ability;

14

15 That I am not related to any of the parties
hereto, nor interested in the outcome of the action;

16 That the reading and signing of the deposition
by the witness and the Notice of Filing were not waived.

17

18 WITNESS MY HAND AND SEAL THIS 8TH DAY OF
OCTOBER, 2015.

19

20

BARBARA J. CAREY, RPR

21

Notary Public

22

23

24